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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,709	09/18/2000	Hiroyuki Fujita	001200	4404

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EXAMINER	
GUPTA, ANISH	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/663,709	FUJITA, HIROYUKI	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 7-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12-22-03 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

3. Claims 1-4, 7-8 remain rejected under 35 U.S.C. 102(b) as being anticipated by Yokoyama et al. for the reasons set forth in the previous office action and the reasons set forth below.

The claims are drawn to a angiotensin converting enzyme inhibitor.

In the response dated, 12-22-03, Applicants argued that the reference does not teach a composition wherein the molecular weight of the 5000 was "at most 10% by weight." Applicants have submitted a declaration that would indicate that the supernatant A contains "21% by weight of the polypeptide having a molecular weight of at least 5,000." In the declaration, submitted by Dr. Fujita, the bonito is subjected to thymosin digestion with subsequent centrifugation. Gel chromatography was used on the supernatant obtained to determine the molecular weight. The molecular weight obtained disclosed that there was present about 21%. Thus, in light of the declaration, it is stated that the product obtained in the reference is not the same as that claimed in the instant application.

Applicant's arguments filed 12-22-03 have been fully considered but they are not persuasive.

First, Applicants declaration procedure is not commensurate in scope to the procedure outlined in the reference. The reference discloses that the ACE inhibitory peptides were isolated using chromatographic procedure. Even after isolation, the peptides maintained their respective activity. Indeed, table IV on page 1543, disclose the IC50 values of the peptides from the digest after isolation. Thus, the purification procedure would lead to a digested product that contained less 10% of polypeptides having a molecular weight of 5000. Applicants have not demonstrated that the isolation procedure outlined in the reference would not lead to the claimed product.

The rejection is maintained.

New Grounds For Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-4 and 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a composition wherein the "content having a molecular weight of at least 5000. . ." It is unclear from the claim what the molecular weight is denoted as. That is, is the measure of molecular weight Daltons, kilodaltons, etc...?

In claim 1, the claim recites that there is present "oligopeptide(s)" and "a polypeptides." The claim thus, states that there maybe present many oligopeptides but only a single "polypeptide."

However, the membrane step implies that there are more the "a polypeptide" present in the composition. It is unclear from the claim how many "polypeptide[s]" are present.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-4 are 7-8 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making

the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

In the instant case, the claims are drawn to angiotensin converting enzyme inhibitor containing a mixture of oligopeptides and "a polypeptide" obtained dried fish. Further, only 10% of the polypeptides have a molecular weight of 5000 or more. This generic statement polypeptides and oligopeptides fails to adequately describe a structural feature common to the genus since the only common feature would be an amide bond between the amino acids. Further, the polypeptide are not limited to any specific class of compounds for which one could readily obtain physical and/or chemical properties or functional characteristics thereby obtaining some insight as to the structure of the desired proteins or polypeptide. The specification provides some examples of oligopeptides and claims these oligopeptides. However, these peptides are limited to small four to nine amino acid peptides. Beyond these small peptides, the specification does not provide any written description of other peptides that would qualify as a oligopeptides. The specification is completely silent on the "polypeptides." It is clear from the claims that oligopeptides and polypeptides are structurally distinct from one another. However, the specification fails to provide any physical and/or chemical properties or functional characteristics for these peptides. The specification, as a whole, does not sufficiently provide ample definition, such as by structure, formula, or chemical name, of the claimed subject matter sufficient to distinguish these "polypeptides" from other peptides. Accordingly, the disclosure lacks sufficient written description to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claim 1 is a broad generic with numerous variants. An oligopeptide or polypeptide obtained from a dried fish such as bonito is inclusive of numerous peptides. The limitations of the process to isolate the desired peptides does not substantially limit the number of species or variation of species encompassed by

claims since the claim is a product claim and is not limited by the process of making or manufacture. The only physiochemcal properties recited are that 90% of the peptides have a molecular weight of less 5000. This limitation, however, does not give any insight as to the structure of the peptides disclosed. The peptides can be inclusive of any number of amino acids chosen from any naturally occurring amino acids. In this case, though the claims may recite a method of obtaining the peptide and some characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the sequence. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification provides only handful of examples for oligopeptides and no examples of "polypeptides." The small genus exemplified does not provide ample written description to any peptide, regardless of amino acid length, obtained dried fish.

It is acknowledged that the MPEP, citing Fiers v. Revel, 984 F.2d 1164, 1169, (Fed. Cir. 1993), recognizes that for a product by process claim, the written description can be fulfilled by the process used to produce that product. However, the Federal Circuit has also stated that description requirement may not be satisfied for a class of compounds, "even though the specification might have indirectly enabled one skilled in the art to make and use the entire class. . . .[I]t is possible for a specification to enable the practice of an invention as broadly as it is claimed, and still not describe that invention." Application of DiLeone, 436 F.2d 1404, 1405 (C.C.P.A. 1971). The Court went on to state, in a footnote that, "consider the case where the specification discusses only compound A and contains no broadening language of any kind. This might very well enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B and C has not been described." Id. This is rather analogous to the instant application. Applicants have described only a small number of species and a method of making these compounds. The method of making might

be enabled to make the entire class desired, but the entire class has not been described to the extent that one could conclude that Applicant was in possession of the claimed invention. Furthermore, in Fiers, the Court stated that for a product claim drawn to a DNA, "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Fiers 984 F.2d at 1170.

In conclusion, the description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, the examples provided in the specification cannot constitute written description to any peptide as encompassed by the claims. Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

6. Claims 1, 3, 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Yasumoto (JP06298794).

The claims are drawn to a angiotensin converting enzyme inhibitor.

The reference teach angiotensin converting enzyme inhibitor peptide obtained from dried bonito (see page 1 under detailed description). The reference states that the peptide is obtained by hydrolyzing the bonito with thermolysin (see page 1 under detailed section). The reference further

states that peptides that cause bitter taste can be removed using a synthetic absorbent (see page 2 of detailed). When people ingested the peptide, little bitterness was expressed (see page 4). Thus, the reference anticipate the claimed invention, since the reference teach the same source, bonito, the same method of making, hydrolysis with thermolysin, and same characteristics as the instant application, no bitterness.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can normally be reached on (571) 272-0961. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

5/1/04

Anish Gupta
Patent Examiner